located from the first location for analysis. A preferred version of applicants' device includes a strip having a handle end and a collection end. The collection end has attached thereon a collection pad for collecting and drying a liquid biological sample containing the analyte. The collection pad is made of sponge-like polyvinyl alcohol. This sponge-like polyvinyl alcohol is advantageous in its ability, relative to other materials, to absorb and dry large quantities of a liquid sample (e.g., urine). It is also advantageous in that it is substantially non-reactive and compatible with a blocking agent such as BSA. In comparison to other materials, these advantages allow the sponge-like polyvinyl alcohol to be used for the measurement of a very dilute analyte in a liquid biological sample (e.g., microalbumin in urine).

Application Status

Claims 19-21, 24-27 and 29-42 were pending in the subject application. Claims 19, 21, 24-27 and 29-42 were rejected under 35 U.S.C. 103(a), as being unpatentable over U.S. Patent No. 5,609,160 (Bahl) in view of U.S. Patent No. 5,728, 350 (Kinoshita). Claim 20 was rejected under 35 U.S.C. 103(a) as being unpatentable over Bahl in view of Kinoshita and further in view of U.S. Patent No. 5,976,895 to Cipkowski (Cipkowski). No claims were allowed.

No claims have been added, cancelled, or amended by this response. Therefore, claims 19-21, 24-27 and 29-42 remain before the examiner for consideration.

Rejection Under 35 U.S.C. § 103

In the Office Action, claims 19, 21, 24-27 and 29-42 were rejected under 35 U.S.C. 103 (a) as being unpatentable over Bahl in view of Kinoshita. More specifically, the Office Action stated:

> Bahl et al. '160 teach a fluid sample collection device comprising a plastic frame having a handle end (30, 40) and a collection end. The plastic frame is rigid enough to be held by the user, as in claims 25 and 26. The device contains an absorbent cotton (cellulosic) pad (50) for collecting the sample. There are openings (32, 42) through the collection end of the device such that the absorbent pad is exposed and capable of collecting the sample. The device also contains an additional opening (28), which allows the oral sample to be extracted during centrifugation.

The Office Action points out that Bahl fails to teach polyvinyl alcohol as the absorbent material, as recited in claims 19 and 27-32, but relies on Kinoshita to provide the motivation to combine the device of Bahl with a sample receiving part made of polyvinyl alcohol, to arrive at the claimed invention. More particularly, as stated in the Office Action:

> Kinoshita et al '350 teaches a test kit having an absorbent sample receiving part on a support material. The sample receiving part is made of water absorbing fibrous material, such as polyvinyl alcohol. See col. 3, lines 46-63. ... It would have been obvious to one of ordinary skill in the art to use the polyvinyl alcohol material disclosed by Kinoshita et al. '350 in the Bahl et al. device to provide enhanced absorbency for the sample.

This rejection is incorrect because the teachings of Bahl and Kinoshita are not properly combinable for the purposes of 35 USC 103. In particular, (a) neither Bahl or Kinoshita suggest the desirability of combining their teachings, and (b) modification of the Bahl device with the polyvinyl alcohol material disclosed by Kinoshita would render the Bahl device unsatisfactory for its intended purpose.

Neither Bahl or Kinoshita Suggest the Desirability of Combining their Teachings

Citing In re Mills (916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990)), MPEP (8th Edition) 2143 provides "[t]he mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." The Bahl device is designed to enable detection of antibodies, antigens, viruses

and the like contained in oral fluid samples, subsequent to in-home collection of such samples, and mailing of same to a laboratory facility. Upon arrival of the device at the laboratory, the liquid sample, bathed in a preservative, is recovered from the device by centrifugation within its own mailer. Bahl Col. 1, lines 35-56. During centrifugation, a seal (63) in the mailer (shown in Bahl Figs. 1, 3, 4, 11, 13) breaks open, allowing for recovery and subsequent testing of the fluid sample which is dispersed in the preservative. (See Bahl Col. 2, lines 56-62).

It is apparent from the foregoing that the fluid-absorbing material used for the sample collection pad in the Bahl device must be well-suited both for the collection of the liquid sample from the subject, and for the centrifugation step required for recovery of the sample from the collection pad. The Office Action contends that the motivation to combine the device of Bahl with the polyvinyl vinyl alcohol material disclosed in Kinoshita would have been to "provide enhanced absorbency for the sample." Inadequate absorbency, however, is clearly not a problem in Bahl's device.

fact that there is an indicator indicates as sample uptake problem

For example, Bahl does not indicate that obtaining a sufficient volume of the sample is problematic. In this regard, Bahl (Col 3, line 51-54) states that the pad made of pure 100% cotton "will hold between 0.75 ml and 1.2 ml of the oral fluid sample." Nowhere does Bahl indicate that this volume is insufficient. Moreover, Bahl's device includes an indicator that changes color "only when sufficient oral fluid has been absorbed by the pad as is required for the analytical procedures." Bahl Col. 3, lines 45-49. Thus, Bahl does not suggest the desirability of modifying its collection pad.

Modification of the Bahl Device with the Polyvinyl Alcohol Material Disclosed by Kinoshita Would Render It Unsatisfactory for Its Intended Purpose

Substituting the polyvinyl alcohol material disclosed by Kinoshita for the 100% cotton pad of the Bahl device would hinder collection of an analyte contained therein. Citing In re Gordon (733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)), MPEP (8th Edition) 2143 provides "[i]f [the] proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." Bahl's device and Kinoshita's apparatus differ markedly in their operation. Bahl's device is a sample collection device in which a sample is collected and later removed for analysis. The device itself does not produce test results. In comparison, Kinoshita's apparatus is a test strip which does produce test results. Because of these differences the components in Bahl's device operate differently from those in Kinoshita's apparatus. In particular, Bahl's device is designed to both collect and release a sample, while Kinoshita's apparatus is designed only to collect a sample.

Accordingly, as the Office Action notes, "Kinoshita et al '350 teach that polyvinyl alcohol materials are preferred because they have an excellent effect of thickening the liquid sample when the sample is absorbed. Thus, sample is retained more firmly and is difficult to remove. (col. 4, lines 1-5)." If the substitution suggested by the examiner was employed, applicant suspects removal of the sample by the centrifugation step taught by Bahl would be impracticable or perhaps impossible. For these reasons, applicants submit that Bahl and Kinoshita are not properly combinable for the purposes of 35 USC 103. Withdrawal of this rejection is therefore requested.

Sponge-like PVA Sample

Each of the currently pending claims includes the element "a sponge-like material made of PVA." This material provides an important advantage for the claimed device's intended purpose that not all forms of PVA provide. To illustrate, a sample of a foamed, polymerized (i.e., sponge-like) PVA material suitable for use in the device (marked "Exhibit A") is enclosed. In marked contrast to sponge-like PVA, the raw material used to make the polymerized product, i.e., PVA powder, is in the form of a white powder. If water is added to PVA powder, it will dissolve. If spread out on a surface, the PVA solution will dry to a thin film that is capable of absorbing liquid. However, unlike sponge-like PVA material, this film is not easy to handle or convenient for processing in a laboratory. The semi-rigid texture of sponge-like PVA material makes the material suitable for its intended purpose- collecting, drying, and releasing a sample. For example, in the practice of the invention, a portion of the sponge-like PVA material containing the sample can simply be punched out from the device, and the analyte eluted from it.

Conclusion

The currently pending claims are supported throughout the specification and are patentable over the prior art. No new matter has been added. This application is now in full condition for allowance, and such action is respectfully requested.

A petition for a three month retroactive extension of time and the required fee are enclosed. The Commissioner is hereby authorized to charge any underpayment or credit any overpayment of fees under 37 CFR 1.16 or 1.17 as required by this paper to Deposit Account 50-0951.

The examiner is cordially invited to call the undersigned if clarification is needed on any matter within this response, or if the examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,

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